UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al.* *ex rel.* SW CHALLENGER LLC *et al.*, Plaintiffs, - v. - EVICORE HEALTHCARE MSI, LLC, Defendant.	19 Civ. 2501 (VM)

STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA

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PRELIMINARY STATEMENT

The United States of America (the "Government") respectfully submits this Statement of Interest (the "SOI") pursuant to 28 U.S.C. § 517.[1] Although the Government declined to intervene in this case, it remains the real party in interest brought under the False Claims Act, 31 U.S.C. § 3729 *et seq*. (the "FCA"). *See U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 934 (2009).[2]

In the Second Amended Complaint, the *qui tam* relators ("Relators") allege that defendant eviCore, which contracted with Medicare Part C plans to conduct medical necessity review of requested treatments, routinely gave improper approvals to medically unnecessary treatments without actually undertaking any clinical review.[3] As a result, according to Relators, eviCore caused Medicare Part C plans to pay for unnecessary medical treatments. *See infra* at 4.

EviCore has moved to dismiss the SAC pursuant to Rules 12(b)(6) and 9(b), arguing, *inter alia*, that it fails to allege "an essential element of an FCA violation" — "the submission of a claim." Def. Br. at 10-12. According to eviCore, because the Government pays Part C plans "based on [patients'] *health conditions* (diagnoses)," rather than "*services provided*," the SAC does not "plausibly allege" the submission of "false claims to the government" even if the Court accepts as true the allegations that eviCore improperly caused Part C plans to approve "payment of [medically unnecessary] services." *Id*. at 11 (emphasis in original).

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[1] 28 U.S.C. § 517 provides that the Attorney General may send an "officer of the Department of Justice … to any State or district in the United States to attend to the interests of the United States in a suit pending in a court of the United States, or in a court of a State, or to attend to any other interest of the United States."

[2] *See also U.S. ex rel. Mergent Services v. Flaherty*, 540 F.3d 89, 93 (2d Cir. 2008) (recognizing that because FCA violations involve "the use of fraud to secure payment from the government," the injury, as well as "lion's share of [damages]," accrue to the Government).

[3] This SOI refers to the Second Amendment Complaint as the "SAC," the defendant's memorandum of law in support of its motion to dismiss as the "Def. Br.", and the relators' brief in opposition to the motion to dismiss as the "Opp. Br."

The Government takes no position on the overall merit of eviCore's motion to dismiss, but submits this SOI solely to clarify relevant points regarding the Medicare Part C program and claims made thereunder. As set forth below, eviCore advances an unduly narrow view of whether payment requests made to Part C plans by subcontractors like eviCore are "claims" under the FCA. Specifically, eviCore does not address 31 U.S.C. § 3729(b)(2)(A)(ii), an FCA provision enacted in 2009 to ensure that the FCA applies to frauds against federal programs irrespective of whether claims are "presented" to the Government. *See infra* Pt. I.

Under *both* prongs of the FCA's definition of "claim," and in light of the structure and features of the Medicare Part C program, eviCore's allegedly improper approvals of medically unnecessary treatments could result in false claims in three ways — *first*, by causing Part C plans to pay healthcare providers for treatments that do not qualify for coverage because they are not medically necessary; *second*, by causing Part C plans to pay eviCore itself for clinical reviews that were not performed or were performed in violation of regulatory or contractual requirements; and, *third*, by causing Part C plans to submit invalid diagnosis data or cost data directly to the Centers for Medicare and Medicaid Services ("CMS"). *See infra* Pt. II. Accordingly, while it is correct that Part C plans receive Medicare payments based in part on the diagnoses they submit to CMS, the plans "obtain diagnosis codes from healthcare providers after these providers" perform treatments. *U.S. ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 672 (9th Cir. 2018). Improper approvals of medically unnecessary treatments by eviCore, therefore, can cause a Part C plan not only to improperly pay for the treatments, but also to submit invalid "diagnosis codes from [the] provider" for payment calculation purposes. *See infra* 3–4. Further, in the annual contract bidding process, CMS calculates payment to Part C plans based, in part, on the plans' healthcare coverage and administrative costs. Improper approval of treatments by eviCore, thus, also can result in submission of inaccurate cost data to CMS by the plans. *See id*.

BACKGROUND

A. BASIC STRUCTURE OF THE MEDICARE PART C PROGRAM

Medicare Part C is an alternative to Medicare's traditional coverage of hospital and out-patient services, which are commonly referred to as Medicare Part A and Part B, respectively. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Under Medicare Part C, CMS contracts with private insurance carriers to provide Medicare beneficiaries with coverage for the types of medical services they would otherwise receive under the traditional Medicare program. *See Cares Cmty. Health v. U.S. Dep't of Health & Hum. Servs*., 944 F.3d 950, 953 (D.C. Cir. 2019); *see generally* 42 U.S.C. §§ 1395w-21 to -28.

Part C plans administer the federal Medicare program in return for payments from CMS, which are disbursed on a monthly, capitated (per beneficiary, not per service) basis. *See* 42 U.S.C. § 1395w-23. CMS calculates the capitated monthly payments to a Part C plan using a "base rate" for the plan's Part C beneficiaries and then applies adjustments based on each beneficiary's "risk score." *See id*. § 1395w-23(a)(1)(B)–(C); 42 C.F.R. §§ 422.304(a)(1)(i), 422.308(c).

To determine a Part C plan's "base rate" in a given contract year, CMS uses a bidding process that considers, *inter alia*, data on the plan's per-enrollee costs from the two preceding years. *See*, *e.g.*, Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2020 (Apr. 5, 2019) at 7, 9, 43; *see generally U.S. ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1025 (N.D. Cal. 2020). Further, to calculate a patient's "risk score" for a specific year, CMS considers demographic factors like age and sex as well as the patient's health status, which is based on diagnosis codes representing the medical conditions for which the patient received treatment in the preceding year. *U.S. ex rel. Swoben v. United Healthcare Ins*., 848 F.3d 1161, 1167–68 (9th Cir. 2016).

More specifically, when a hospital or physician seeks payment for providing treatment to a Part C beneficiary, they submit diagnosis codes to the beneficiary's Part C plan. "In turn, [the Part C plans] report the diagnosis codes that they receive [from the hospital or physician] to [CMS] for use in the risk adjustment model that is the key to calculation of capitation [payment] rates." *Sutter Health*, 444 F. Supp. 3d at 1022-23; *see also Silingo*, 904 F.3d at 672; *Swoben*, 848 F.3d at 1167–68.

Finally, as is the case under traditional Medicare, Part C plans are not obligated to pay for treatments that have been determined not to satisfy the "medical necessity" standard. *See* 42 C.F.R. § 422.566(d). To assist in making medical necessity determinations, Part C plans may pay subcontractors like eviCore to perform prospective clinical review of treatment requests. *See U.S. ex rel. Nedza v. Am. Imaging Mgmt, Inc.*, No. 15 C 6937, 2020 WL 1469448, at *3 (N.D. Ill. Mar. 26, 2020) (providing an overview of the medical necessity review process in the Medicare Part C context). In recognition of the fact that Part C plans often need to rely on "first-tier [and] downstream" entities like eviCore to assist in these reviews, Medicare Part C regulations expressly mandate that Part C plans must require these entities to agree to "comply with all applicable Medicare laws, regulations, and CMS instructions" in their contracts with the plans. 42 C.F.R. § 422.504(i)(4)(v).

B. RELATORS' FRAUD ALLEGATIONS AGAINST EVICORE

Relators, who worked as clinical reviewers at eviCore, allege that eviCore contracts with Medicare Part C plans to "provide utilization management services and review prior authorization requests." SAC ¶ 10. A prior authorization request involves a healthcare provider seeking approval from eviCore before providing treatment to a Medicare Part C beneficiary "in order to ensure that the costs of the [treatment] will be covered by [the beneficiary's Part C plan]." *Id.* ¶ 88. In this context, eviCore's role is to "determine whether services that are

covered and paid for by … Medicare [Part C] Plans" comply with the requirement of being medically necessary. *Id*. ¶ 84; *see also id*. ¶ 66.

Relators allege, however, that eviCore did not provide "meaningful review" of medical necessity before approving treatments for coverage by Part C plans. *Id*. ¶ 98. Instead, according to Relators, eviCore routinely directs its reviewers to "ignore acceptable standards of clinical practice" and "simply auto-approve" many types of treatments. *See id*. ¶¶ 99–112. Relators further allege that, starting in 2017, eviCore "implemented artificial intelligence systems" that "restrict[] the ability of Clinical Reviewers to conduct a meaningful review" and, thereby, expedite its "fraudulent auto-approve process." *Id.* ¶¶ 113–23.

As result of its alleged conduct, according to Relators, eviCore has caused Medicare Part C plans to cover and pay for services that were not "medically reasonable and necessary." *See id*. ¶ 130. In addition, Relators also allege that eviCore itself fraudulently obtained "millions of dollars" from Part C plans for performing "prior authorization reviews which either never happened or were undertaken in a sub-standard, worthless fashion." *Id*. ¶ 131.

ARGUMENT

POINT I

UNDER THE FCA, "CLAIMS" INCLUDE PAYMENT REQUESTS MADE TO CONTRACTORS, LIKE MEDICARE PART C PLANS, THAT OPERATE FEDERAL PROGRAMS WITH GOVERNMENT FUNDS

EviCore argues that the SAC fails to allege the "the submission of a claim." Def. Br. at 10. The core premise of eviCore's argument is that the FCA requires Relators to "plausibly allege that eviCore's [conduct] caused [Part C plans] to submit false claims to the government." *Id*. at 11. However, the FCA does not limit "claims" only to payment requests submitted directly to the Government, *see* 31 U.S.C. § 3729(b)(2)(A)(i); instead, "claims"— as defined in 31 U.S.C. § 3729(b)(2)(A)(ii) — also can include requests submitted to entities like Part C plans that receive funding from the Government to operate federal programs like Medicare.

Indeed, as the Second Circuit recognized, section 3729(b)(2)(A)(ii) "defines claim … broadly … to encompass demands or requests made to a contractor, grantee, or other recipient" as long as "two conditions" are met — "first, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest," and "second, if the [] Government provides or has provided any portion of the money or property requested or demanded, or will reimburse [the recipient] for any portion of the money or property which is requested[.]" *U.S. ex rel. Bishop v. Wells Fargo & Co*., 943 F.3d 588, 601-02 (2d Cir. 2019) (internal quotation marks omitted); *accord U.S. ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 706 (S.D.N.Y. 2018).

Legislative history, moreover, shows that Congress adopted this broad definition with the purpose of making clear that payment requests need not be directly "presented" to the Government to qualify as "claims" under the FCA. Specifically, through the 2009 FCA amendments, Congress expressly rejected a 2004 D.C. Circuit opinion in which that Court held that fraudulent claims made upon Amtrak could not give rise to liability under the pre-2009 version of the FCA, despite Amtrak's status as a federal grantee, because the claims were not "presented" directly to the Government. *See U.S. ex rel. Totten v. Bombardier Corp*., 380 F.3d 488, 492-93 (D.C. Cir. 2004).

Congress concluded that, by requiring direct "presentment," *Totten* enunciated an erroneous interpretation of the FCA. *See* S. Rep. No. 110-10 at 10-11. "[T]o correct and clarify" the proper scope of the FCA, and as part of the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, Congress amended the definition of "claim" to include payment requests made to contractors, grantees, and other recipients of federal funding without regard to "presentment" to a governmental entity. *See* S. Rep. No. 110-10 at 10-11; *see also U.S. ex rel. Garbe v. Kmart Corp*., 824 F.3d 632, 638 (7th Cir. 2016) (recognizing that FERA's "new language underscored Congress's intent that FCA liability attach to any false claim made to an

entity implementing a program with government funds, regardless of whether that entity is public or private"). Moreover, Congress intended for this amendment to ensure that the FCA applies to the Medicare context specifically, where the "Government [is] relying on private contractors to disburse funds," *see* 155 Cong. Rec. H5260-01, 2009 WL 1228046 (Rep. Sensenbrenner), as well as to "subcontractors paid with government money" that commit fraud, *see* 155 Cong. Rec. S1679-01, 2009 WL 275706 (Sen. Leahy, introducing the 2009 FCA amendment).

In short, the text of 31 U.S.C. § 3729(b)(2)(A)(ii) and FERA's legislative history both make clear that the direct "submi[ssion of] false claims to the government" is not necessary for stating an FCA claim, and that a request made to a contractor like a Medicare Part C plan is encompassed within the meaning of "claim" under the FCA.

POINT II

EVICORE'S ALLEGED IMPROPER APPROVALS OF MEDICALLY UNNECESSARY TREATMENTS COULD GIVE RISE TO FALSE CLAIMS UNDER 31 § U.S.C. § 3729(b)(2)(A)

In the context of the Medicare Part C program, a subcontractor like eviCore's improper approval of a medically unnecessary treatment ***could*** give rise to ***three*** types of false claims under 31 U.S.C. § 3729(b)(2)(A).[4] First, insofar as an improper approval results in a healthcare provider billing a Part C plan for the medically unnecessary treatment, that payment request is a "claim" under § 3729(b)(2)(A)(ii). Second, when eviCore subsequently invoices the Part C plan for conducting a medical necessity review even though no "meaningful review" occurred, that invoice also is a "claim" under § 3729(b)(2)(A)(ii). Finally, when the Part C plan

[4] EviCore suggests that the sufficiency of its medical necessity reviews cannot be examined in this case because medical necessity is "not defined in the Medicare Act" or CMS regulations. *See* Def. Br. at 5 –6. This is incorrect. As another court recently recognized, "Medicare statutes, regulations, and [program manuals]" require Part C plans and their clinical review subcontractors to make "individualized coverage determinations based on medical necessity." *Nedza*, 2020 WL 1469448, at *8. Further, if a subcontractor utilizes a clinical review process that "violated the requirement … to make coverage determinations based on individual medical necessity," it can be held liable under the FCA. *Id*.

transmits to CMS inaccurate diagnosis codes that the Part C plan received from the treating provider, thus affecting CMS's calculation of the appropriate "risk score," the transmission of the invalid diagnosis data is a "claim" under § 3729(b)(2)(A)(i).[5]

In the first two scenarios, § 3729(b)(2)(A)(ii) applies because of the structure of the Medicare Part C program. Specifically, Part C plans are required by statute to contract with CMS in order to receive payments. *See* 42 U.S.C. § 1395w-27(a). The plans, accordingly, are "contractors" within the meaning of § 3729(b)(2)(A)(ii). Further, when a healthcare provider bills a Part C plan for treating a beneficiary, or when eviCore invoices the plan for performing medical necessity review, both the bill and invoice relate to the operation of the Medicare Part C program. These requests, thus, are for payments "used … to advance a Government program" — namely, Medicare. *Id*. § 3729(b)(2)(A)(ii); *see also Garbe*, 824 F.3d at 638 (recognizing that, post-FERA, "FCA liability" can arise from prescription drug bills submitted to Medicare Part D plans because those plans are "implementing a government program[.]"). Finally, as noted above, CMS makes monthly capitated payments to Part C plans "in exchange for" the plans' "provid[ing] Medicare benefits." *Silingo*, 904 F.3d at 672; *see generally* 42 U.S.C. § 1395w-23. The "United States Government," therefore, "provides … [a] portion of the money [] requested" by the provider and by eviCore in the first two scenarios. 42 U.S.C. § 3729(b)(2)(A)(ii)(I); *see also Grubea*, 318 F. Supp. 3d at 706 ("it is not necessary to show that the funds were provided

[5] At this stage of litigation, there is no record from which to determine if the alleged improper approval of treatment by eviCore led to the transmission of invalid diagnosis codes to CMS. However, a "meaningful" medical necessity review likely involves assessing whether the patient actually has the medical condition for which treatment is requested and whether the reported diagnosis overstates the severity of the patient's medical condition.

Failing to conduct these assessments, in turn, could result in the approval of medical treatment for a patient who either does not have the reported diagnosis or whose medical condition is less severe than indicated by the reported diagnosis. In either case, the Part C plan could receive inaccurate diagnosis codes from the provider in connection with requesting payment for the treatment and then transmit the inaccurate codes to CMS.

specifically to pay defendants' claims. Rather, the FCA applies as long as any portion of the claim is or will be funded by U.S. money"); *Bishop*, 943 F.3d at 601-02; *Garbe*, 824 F.3d at 638.

In the third scenario, the transmission of diagnosis codes to CMS by a Part C plan is a "claim" under 31 U.S.C. § 3729(b)(2)(A)(i). See *Sutter Health*, 444 F. Supp. 3d at 1086 n. 505 (recognizing that diagnosis codes submitted to CMS by Part C plans "can [] constitute 'claims'" for FCA purposes). This is both because the data is being provided directly to the Government and because, as noted above, the reporting of diagnosis data reports to CMS "for use in [Medicare Part C's] risk adjustment model [] is the key to calculation of capitation rates." *Sutter Health*, 444 F. Supp. 3d at 1023. As described above, CMS uses the capitation rates it calculates to determine how much to pay the Part C plan for each particular beneficiary. Accordingly, insofar as Relators have sufficiently alleged that eviCore's improper approval of medically unnecessary treatments resulted in Part C plans' transmission of inaccurate diagnosis codes to CMS (as to which the Government express no view), those inaccurate codes can be considered false claims under the FCA.

Finally, as discussed above, *see supra* at 4, Medicare Part C plans also submit two prior years' worth of cost data to CMS each year as part of the annual bidding process for purposes of determining the "base rates" for the plans in the following year. *See generally Sutter Health*, 444 F. Supp. 3d at 1025. Therefore, to the extent that eviCore's alleged improper approvals caused Part C plans to incur meaningfully higher costs as result of covering medically unnecessary treatments, such conduct also could have resulted in the submission of inaccurate cost data to CMS by the plans in the annual contract bidding process.

CONCLUSION

For the reasons set forth above, the Government respectfully submits that the Court should not adopt defendant eviCore's incorrect argument that no false claims could arise from eviCore's allegedly improper approval of medically unnecessary services for payment by Medicare Part C plans.

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Respectfully submitted,

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